Remarks/Arguments

Claims 13-18, 41-43, and 45 are pending. Claims 6-12, 19-22, 24-40, and 46-50 stand withdrawn as drawn to non-elected subject matter.

Claims 1-5 have been canceled without prejudice. Applicants expressly reserve the right to pursue the subject matter of claims 1-5 in a continuation, continuation-in-part, or divisional application.

Claims 41 and 45 have been amended to depend from claim 13. No new matter has been added to these claims.

Claims 15 and 17 have been amended to restore the claims to their original form. The claims in their original form incorporate by reference Figures 3 and 4, respectively. In a non-final office action dated April 18, 2005, the Office rejected claims 3, 5, 15, and 17 under 35 U.S.C. § 112, second paragraph as allegedly indefinite "because the claims are not self-contained." Office Action dated April 18, 2005, p. 9, ll. 3-10. In order to cooperate with the Office, Applicants chose to amend the claims to insert the figures directly into the claims, rather than incorporate them by reference. Amendment dated December 7, 2005. Now, the Office objects to claims 3, 5, and 15, stating that "drawings cannot be incorporated in the claims." Office Action dated March 3, 2006, p. 1, l. 9. Therefore, Applicants currently amend claims 15 and 17 to restore the incorporation of the figures by reference, as allowed by M.P.E.P. § 2173.05(s) and explained below. In doing so, no new matter has been added. As to claims 3 and 5, the objection has been rendered moot by the cancellation of the claims.

Incorporation of a drawing into a claim by reference is appropriate "where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." M.P.E.P. § 2173.05(s); *In re Fressola*, 27 U.S.P.Q.2d 1608 (Bd. Pat. App. & Interf. 1993). In this case, it is not practical for Applicants to describe in words the powder X-ray diffraction and infrared spectra in as detailed a form as they appear in Figures 3-4, including peak/band positions, intensities, and shapes, among other details. As such, it is both more comprehensive and concise to incorporate the figures by reference into the claims than to attempt to describe all of the intricacies of the powder X-ray diffraction and the infrared spectra in words. Applicants note that

Examiner Morris has recently allowed claims which incorporate X-ray powder diffraction and nuclear magnetic resonance spectra by reference. *See* U.S. patent No. 6,645,982; U.S. patent No. 6,509,347; U.S. patent No. 5,834,502. Accordingly, the objection to claims 3, 5, and 15 cannot stand and should be withdrawn.

In addition, because Applicants had inserted copies of the figures into the claims, the Office now objects to the drawings. The Office states: "Drawings must be on separate sheets...Corrected drawing sheets in compliance with 37 C.F.R. 1.121(d) are required in reply to the Office Action to avoid abandonment of the application." Office Action dated March 3, 2006, p. 2, ll. 9-11. This requirement is improper. By inserting copies of the figures into the claims, Applicants have not amended the drawing sheets. The drawing sheets as filed on March 12, 2004 were accepted by the Office. Office Action dated April 18, 2004, p. 9, l. 21. Because the drawing sheets have not been amended since acceptance, the Office can have no proper objection to them now.

Claims 1-5, 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 102 (a), (b), and/or (e) as allegedly anticipated by U.S. publication No. 2003/0036554 to Avrutov et al. ('554 publication"), U.S. patent No. 6,723,852 to Maimo ("'852 patent"), U.S. patent No. 4,758,579 to Kohl et al. ("'579 patent"), and Kohl, et al., *J. Med. Chem.*, 1992, 35, pp. 1049-1057 ("Kohl article"). This rejection has been rendered moot as to claims 1-5 by the cancellation of the claims. As to the remaining claims, Applicants respectfully traverse.

To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art, and must disclose every element of the challenged claim. *Motorola Inc. v. Interdigital Technology Corp.*, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997); *PPG Industries Inc. v. Guardian Industries Corp.*, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 231 U.S.P.Q. 160 (Fed. Cir. 1986). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). An anticipatory reference must also enable one of ordinary skill in the art as to the claimed subject matter.

Each one of claims 13-18, 41-43 and 45 encompasses a "crystalline solid pantoprazole" having a particular powder x-ray diffraction ("PXRD") pattern, a particular infrared ("IR") pattern or a pharmaceutical composition thereof.

As previously argued, the '852 patent, the '579 patent, and the Kohl article each disclose pantoprazole. *See* '852 patent, example 18, col. 9, ll. 38-53; '579 patent, col. 5, ll. 23-24, col. 35, ll. 10-13; Kohl article, p. 1052, Table I, compound 1a. Likewise, the '554 publication discloses pantoprazole. *See* '554 publication, example 4, p. 4, ¶ 50. None of these references discloses a PXRD or IR pattern for pantoprazole, as recited in claims 13-18, 41-43, and 45. Since not one single reference discloses each and every element of the claims, the legal standard for anticipation under 35 U.S.C. § 102(a), (b) and/or (e) has not been satisfied.

Nevertheless, the Office argues that claims 13-18, 41-43, and 45 are anticipated by the bare disclosure of the compound pantoprazole in the references because "a novel chemical product is identified first by its 'chemical nature,' i.e., elemental and atom content." Office Action dated March 3, 2006, p. 3, ll. 23-24. This argument is inapposite because it is contrary to law and it ignores recitations of the claims. The claims do not simply recite the compound pantoprazole, as the Office suggests. Instead, the claims recite pantoprazole having a particular PXRD pattern or PXRD pattern and IR spectrum. All claim recitations must be considered when assessing patentability under 35 U.S.C. § 102. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1462 (Bd. Pat. App. & Interf. 1990).

Moreover, the Board of Patent Appeals and Interferences, in an unpublished decision, has held it improper to reject claims to a novel crystalline form of a compound solely based upon the prior art disclosure of the compound *per se*. *Ex parte Havens*, Appeal No. 2001-0091, 2003 WL 21279863 (Bd. Pat. App. & Interf.) (a copy of which is attached hereto as "Attachment A" for the Examiner's convenience). In *Havens*, the Board reversed the rejection of claims to novel crystalline forms S and T of delavaridine mesylate as anticipated by the prior art disclosure of delavaridine mesylate *per se*, concluding that "to anticipate the claims, the prior art must disclose delavaridine mesylate in the S and T crystal forms." *Id.* at *2.

Therefore, because the references cited by the Office do not disclose pantoprazole with the recited PXRD patterns or PXRD patterns and IR spectra, the references cannot anticipate the claims. Accordingly, the rejection of claims 1-5, 13-18, 41-43, and 45 under 35 U.S.C. § 102(a), (b) and/or (e) cannot stand and should be withdrawn.

Claims 1-5, 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over the '554 publication, '852 patent, '579 patent, and the Kohl article, in view of general reference materials Haleblian, et al., *J. Pharm. Sci.*, 1969, 58, pp. 911-929 ("Haleblian"), Muzaffar, et al., *J. Pharmacy*, 1979, 1(1), pp. 59-66 ("Muzaffar"), Rouhi, *Chem. & Eng'g News*, Feb. 2003, pp. 32-35 ("Rouhi"), U.S. Pharmacopeia, 1995, pp. 1843-1844 ("USP 1995"), Jain, et al., *Indian Drugs*, 1986, 23(6), pp. 315-329 ("Jain"), Taday, et al., *J. Pharm. Sci.*, 2003, 92(4) ("Taday"), and Concise Encyclopedia Chemistry, 1993, pp. 872-873 ("Encyclopedia"). This rejection has been rendered moot as to claims 1-5 by the cancellation of the claims. As to the remaining claims, Applicants respectfully traverse.

The Federal Circuit in *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999), set forth three requirements to make out a *prima facie* case of obviousness under 35 U.S.C. § 103(a) in view of the prior art. In order for a claim to be *prima facie* obvious, the Office must establish: (i) a teaching or suggestion in the prior art to modify or combine references to form the claimed invention, (ii) a reasonable expectation of success taught or suggested in the prior art, and (iii) all of the elements of the claimed invention are found in the prior art. *Id.*; *see also* M.P.E.P. § 2143. The Office can satisfy its burden to establish a *prima facie* case of obviousness based on a combination of references "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The need for specificity is paramount. *In re Sang Su Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). "Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected the components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

The Office asserts that the '554 publication, '852 patent, '579 patent, and the Kohl article "teach the crystal forms of the instant known compound as well as the pharmaceutical compositions." Office Action dated March 3, 2006, p. 4, l. 23 to p. 5, l. 1. In particular, the Office points to example 4 of the '554 publication and claim 22 of the '579 patent. *Id.*

Applicants note that example 4 of the '554 publication discloses the synthesis of pantoprazole in the form of "an almost white solid" via the selective oxidation of 5-difluoromethoxy-2-[3,4-dimethoxy-2-pyridyl) methyl]thio]-1H-benzimidazole. '554 publication, p. 4, ¶ 50. The '554 publication does not disclose whether the "almost white solid" is crystalline. The '554 publication also does not disclose pharmaceutical compositions.

Applicants note that claim 22 of the '579 patent recites "A compound according to claim 1 which is 5-difluoromethoxy-2-[3,4-dimethoxy-2-pyridyl) methylsulfinyl]-1H-benzimidazole or a pharmacologically-compatible salt thereof." '579 patent, col. 35, ll. 10-13. The '579 patent does not disclose any data as to the physical structure of the disclosed pantoprazole.

Likewise, the '852 patent discloses the compound pantoprazole. '852 patent, example 18, col. 9, ll. 38-53. The pantoprazole is isolated in solid form from solution by evaporation of the solvent. *Id.* The '852 patent does not disclose any data as to the physical structure of the pantoprazole. The '852 patent also does not disclose pharmaceutical compositions.

Further, the Kohl article discloses the compound pantoprazole. Kohl article, p. 1052, Table I, compound 1a. The Kohl article discusses crystallization of pantoprazole from a mixture of dichloromethane and diisopropyl ether. *Id.* The Kohl article does not characterize the physical structure of the pantoprazole. The Kohl article also does not disclose pharmaceutical compositions.

Accordingly, the primary references do not "teach the crystal forms of the instant known compound as well as the pharmaceutical compositions," as the Office asserts.

To remedy the deficiencies of the primary references, the Office cites Haleblian, Muzaffar, Jain, and Taday for the general teaching that "compounds exist as polymorphs." Haleblian discusses polymorphism in general, examines the behavior of polymorphs in pharmaceutical dosage forms, and discusses methods used

to study polymorphism. *See* Haleblian, pp. 911-929. Muzaffar discusses polymorphism and examines whether polymorphic forms of compounds exhibit different pharmaceutical properties than amorphous forms of those compounds. *See* Muzaffar, pp. 59-66. Jain discusses polymorphism in general, discusses methods for obtaining and identifying polymorphs, and examines the behavior of polymorphs in the manufacturing and administration of pharmaceutical dosage forms. *See* Jain, pp. 315-329. Taday discusses polymorphism in general and examines the use of terahertz pulse spectroscopy to study the crystalline structures of polymorphs of ranitidine hydrochloride. *See* Taday, pp. 831-838. None of these references discloses pantoprazole, suggests that pantoprazole exhibits polymorphism, or suggests a method of making a crystalline form of pantoprazole.

The Office also cites Rouhi, Muzaffar, USP 1995, and Encyclopedia for the general teaching that "at any particular temperature and pressure, only one crystalline form is thermodynamically stable." Office Action dated March 3, 2006, p. 5, ll. 1-4. Rouhi discusses polymorphism and states that polymorphs tend to convert from less thermodynamically stable to more thermodynamically stable forms. *See* Rouhi, p. 32. Muzaffar mentions that "[a]t any one temperature and pressure, only one crystal form is stable and any other polymorph existing under these conditions will convert to the stable form...." *See* Muzaffar, p. 60, left column. USP 1995 discloses that many pharmaceutical compounds have been found to exhibit polymorphism, and that each polymorphic form is characterized by a unique powder x-ray diffraction pattern. *See* USP 1995, p. 1843, right column. Encyclopedia defines polymorphism in general and states that only one polymorphic form is stable at a given temperature and pressure. *See* Encyclopedia, pp. 872-873. Again, none of these references discloses pantoprazole or suggests that pantoprazole exhibits polymorphism, or suggests a method of making a crystalline form of pantoprazole.

When one skilled in the art considers the '554 publication, '852 patent, '579 patent, and the Kohl article, which disclose the compound pantoprazole *per se*, in view of Haleblian, Muzaffar, Jain, Taday, Rouhi, USP 1995, and Encyclopedia, which discuss aspects of polymorphism in general, he is not motivated to make the claimed crystalline form of pantoprazole. None of these references, either alone or in combination, teaches or suggests that pantoprazole exists in the claimed crystalline form. As the Office even admits, "[n]o method exists to predict the polymorphs of a

solid compound with any significant certainty." Office Action dated March 3, 2006, p. 9, ll. 21-22. Thus, in rejecting the claims as obvious in view of these references, the Office at best has applied an "obvious to try" rationale, and at worst has applied a *per se* rule of obviousness of polymorphs. Both rationales are contrary to law. *See, e.g., In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

The Board, in several unpublished opinions, has repeatedly reversed rejections of claims to polymorphs under 35 U.S.C. § 103 based upon substantially the same *per se* approach applied by the Office in this case. *See Ex parte Meisel*, Appeal No. 2002-0438, 2002 WL 32334598 (Bd. Pat. App. & Interf. October 10, 2002) (attached hereto as "Attachment B"); *Ex parte Havens, supra*; *Ex parte Polniaszek*, Appeal No. 2001-1805, 2003 WL 22282265 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment C"); *Ex parte Gala*, Appeal No. 2001-0987, 2002 WL 851814 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment D").

For example, in *Ex parte Meisel*, the examiner rejected claims to polymorphs of a compound as obvious over a reference disclosing the compound *per se* (Dieter) in view of a general reference discussing polymorphism (Kirk-Othmer). The Board reversed the rejection, concluding:

> Dieter, while teaching the compound that is the subject of the claims is known, does not teach or suggest that the compound has different crystalline structures. Thus, the rejection of record does not set forth any motivation to combine Dieter with Kirk-Othmer because, although Kirk-Othmer does teach that it is known that crystal polymorphism is known generally to exist, **there is no teaching or suggestion in the references that the compound of the claimed invention is known to exhibit such polymorphism.**

Ex parte Meisel, 2002 WL 32334598 at *2 (emphasis added). *See also Ex parte Havens* and *Ex parte Polniaszek* (applying similar analyses).

Not only has the Board reversed obviousness rejections of claims to polymorphs of a compound where the prior art is silent about the compound's ability to exhibit polymorphism, but the Board also has reversed such rejections even where different polymorphic forms of the compound were known to exist.

For example, in *Ex parte Gala*, the Board reversed an examiner's rejection of claims to loratadine polymorphic form 2 as obvious over the prior art disclosure of

loratadine polymorphic form 1. The Board held that the rejection was improper because "the examiner...has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine." *Ex parte Gala*, 2002 WL 851814 at *3. Applicants note that the examiner in *Ex parte Gala* was in Art Unit 1625, the very same art unit in which this application is currently being examined.

Moreover, the Office improperly shifts the burden to Applicants to present evidence of unexpected properties of the claimed crystalline form of pantoprazole by relying on *In re Cofer*, 148 U.S.P.Q. 268 (C.C.P.A. 1965) and *Ex parte Hartop*, 139 U.S.P.Q. 525 (Bd. Pat. App. & Interf. 1962) for the proposition that "product[s] which are merely different forms of known compounds, notwithstanding that some desirable results are obtained therefrom, are unpatentable." *See* Office Action dated March 3, 2006, p. 5, ll. 15-22. This, however, is not an accurate statement of the state of the law. As noted by the Board in *Ex parte Gala*, the court in *In re Cofer* "substantially discredited PTO reliance on the above-quoted proposition of law in Hartop." *Ex parte Gala*, 2002 WL 851814 at *3.

Based on the foregoing arguments, the rejection of claims 1-5, 13-18, 41-43, and 45 under 35 U.S.C. § 103(a) cannot stand and should be withdrawn.

Claims 1-5, 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking in written description. This rejection has been rendered moot as to claims 1-5 by the cancellation of the claims. As to the remaining claims, Applicants respectfully traverse.

To satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563. As long as a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, the written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996). "*Ipsis verbis* disclosure is not necessary to satisfy the written description requirement." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

The Office alleges that the application lacks written description because "there is a lack of description as to whether the pharmaceutical carriers are able to maintain the compound in the polymorphic form claimed," "[t]he specification fails to describe the pharmaceutical compositions claimed in terms of their x-ray diffraction pattern or infrared spectrum data," and "the specification has...not described how all the crystalline forms and compositions being claimed will be maintained and prevented from converting to other forms when used in inhibiting gastric secretion." Office Action dated March 3, 2006, p. 6, ll. 18-19, p. 7, ll. 2-3, p. 8, ll. 15-17.

Each of claims 13-18 encompasses a compound "crystalline solid pantoprazole," and not a pharmaceutical composition. The Office admits that "[t]he x-ray diffraction patterns and infrared spectra on pages 8-11...supports the polymorphic forms of the compounds." Office Action dated April 18, 2006, p. 7, ll. 17-18. Accordingly, the Office cannot properly reject claims 13-18 for lack of written description.

As to claims 41-43 and 45, which encompass pharmaceutical compositions and methods of treatment with the compositions, the Office has not met its burden to establish a lack of written description under 35 U.S.C. § 112, first paragraph.

Applicants' specification as filed is presumed to provide adequate written description for the original claims. M.P.E.P. § 2163.04. In order to rebut this presumption, the Office has the burden of establishing by a preponderance of the evidence "why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *See In re Alton*, 76 F.3d at 1175 (quoting *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976)); M.P.E.P. § 2163.04(I). The Office must set forth express findings of fact to support this conclusion. M.P.E.P. § 2163.04(I).

The Office makes two basic arguments to support its position that the specification lacks written description for the claimed pharmaceutical compositions and methods of treatment: (1) Applicants have produced no evidence to prove that the pantoprazole maintains its crystalline form after manufacturing and/or formulation of the pharmaceutical compositions, and (2) Applicants have produced no evidence to prove that the pantoprazole maintains its crystalline form after administration of the pharmaceutical compositions to patients for the purpose of inhibiting gastric secretion.

To support its first argument, the Office offers the following: "Processing a compound into a pharmaceutical composition **could** create a different polymorph than the polymorphs being claimed;" "manufacturing processes affect polymorphs;" "polymorphic state **may** be changed by incorrect storage or even during tablet preparation;" "one **may** also observe changes in technology or pharmaceutical properties that are due to polymorphic environmental conditions undergone by the product or dosage form." Office Action dated March 3, 2006, p. 6, l. 19 to p. 7, l. 2 (citing Haleblian, Jain, Otsuka, et al., *Chem. Pharm. Bull.* 47(6), pp. 852-856 (1999), Taday, and Doelker[1]) (emphases added).

To support its second argument, the Office offers the following: "[I]t is well recognized in the art that the compound is given to the subject in a physiological environment...there is no description or enabling support that the instant polymorph will be in its physical form and biological activity results from the particular form instead of the solution state of the compound;" "in the aqueous phase, *all physical forms are amorphous*." Office Action dated March 3, 2006, p. 8, ll. 9-10, 15-21 (citing Ulicky, et al., *Comprehensive Dictionary of Physical Chemistry*, 1992, p. 21) (emphasis in original).

The above-cited evidence offered by the Office is no more than mere conjecture, and is not sufficient to establish that one of skill in the art would have reason to doubt the fact that Applicants were in possession of the claimed invention at the time of filing.

Moreover, in order for the evidence to have any bearing on the issue of written description, the Office must read temporal limitations into the claims, *i.e.*, a requirement that the crystalline solid pantoprazole maintain its crystallinity through formulation, administration, absorption, metabolism, and excretion of the pharmaceutical composition. The claims recite no such temporal limitations. Further, for the sake of argument, even if the pantoprazole were to convert to a different form upon formulation or administration of the pharmaceutical composition,

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[1] Applicants note that the Doelker reference is not listed in the "Notice of References Cited" attached to the March 3, 2006 Office Action and is not identified by the Office other than by the shorthand "Doelker." Applicants respectfully request that the Office identify this reference so that Applicants may have the opportunity to fully respond to the issues raised by the Office.

it would fall outside the scope of Applicants' claims. There is no statutory requirement that an applicant describe embodiments that fall outside the scope of the invention as claimed.

Accordingly, the rejection of claims 1-5, 13-18, 41-43, and 45 under 35 U.S.C. § 112, first paragraph as lacking written description cannot stand and should be withdrawn.

While discussing its written description rejection, the Office considers the factors set forth by *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) and states that "[t]aking the...factors into consideration, it is not seen where the instant claims is **enabled** by the instant application." Office Action dated March 3, 2006, pp. 9-11 (emphasis added). Applicants note that the enablement requirement is separate and distinct from the written description requirement of 35 U.S.C. § 112. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991); M.P.E.P. § 2163(I). Therefore, it is improper for the Office to treat written description and enablement as a single basis for rejection. However, for the sake of clarity, Applicants will address enablement of the claims.

To fulfill the enablement requirement of 35 U.S.C. § 112, first paragraph, the patent must disclose enough information about the claimed invention to enable one skilled in the art to make and use it without undue experimentation. *In re Wands*; M.P.E.P. § 2164.01.

The application describes the preparation of the claimed polymorphic form of pantoprazole in sufficient detail to allow one skilled in the art to make and use it without undue experimentation. *See* Specification, pp. 11-12, examples 4-20 (providing specific reaction conditions for the "slurry" procedure for making the claimed compound). The application also describes the claimed pharmaceutical compositions containing the recited polymorphic form of pantoprazole in sufficient detail to allow one skilled in the art to make and use them without undue experimentation. *See* Specification, p. 6, l. 31 to p. 11, l. 4. As such, the disclosures meet the legal standard for enablement set forth in *In re Wands*.

Moreover, a specification "must be taken as in compliance with the enabling requirement of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971). "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made,

to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *Id.* As discussed above, the Office bases its § 112 rejection on mere conjecture. Therefore, the Office has not met its burden to establish reason to doubt that Applicants' disclosure would have enabled one of skill in the art to make and use the claimed invention at the time of filing.

Based on the foregoing arguments, any rejection of the claims under 35 U.S.C. § 112, first paragraph as lacking enablement cannot stand and should be withdrawn.

Claims 1-5, 13-18, 41-42, and 44-45 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly failing to particularly point out and distinctly claim the invention. The rejection has been rendered moot as to claims 1-5 by the cancellation of the claims. As to the remaining claims, Applicants respectfully traverse.

"Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000) (citing *Personalized Media Comm., LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998)). When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989); M.P.E.P. § 2173.05(a). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Personalized Media Comm.*, 161 F.3d at 705, 48 U.S.P.Q.2d 1180 (citing *Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). In other words, the definiteness of the claim language must be analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one of ordinary skill in the pertinent art. *Solomon*, 216 F.3d at 1378 (citing *In re Moore*, 439 F.2d 1232 (C.C.P.A. 1971)).

Claims 2-5, 14-18, 42, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Office:

> [C]laims 2-5, 14-18, 42, and 45 lack antecedent basis for the recited limitations. Contra to applications' arguments in the instant response, claims 1 and 13 fail to clearly claim what is intended by applicants and fail [to] recite any of the claimed limitations.

Office Action dated March 3, 2006, p. 11, ll. 21-23.

Applicants cannot decipher the basis for this rejection. The terminology used in claims 14-18, 42, and 45, *i.e*, "crystalline solid pantoprazole," finds antecedent basis in claim 13, from which the claims depend. Applicants respectfully request that the Office specifically "point out wherein the indefiniteness resides," as required by M.P.E.P. § 707.07(d).

Claims 1-5, 13-18, 41, and 45 also stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because, according to the Office, the claims contain "the trade name pantoprazole" to describe the claimed product.

Pantoprazole is not a trade name. Pantoprazole is a shorthand chemical name for the compound 5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, which is readily recognized by those of ordinary skill in the art. *See Merck Index*, 13th ed., p. 1256, compound 7084 (2001). Further, the term pantoprazole is explicitly defined as "5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" in the specification. Specification, p. 1, ll. 15-17. Pantoprazole is marketed in the form of pantoprazole sodium sesquihydrate by Wyeth under the trade name Protonix®. *See Physician's Desk Reference*, 57th ed., pp. 3461-3466 (2003). Therefore, the Office can have no proper objection to the term pantoprazole as a trade name under M.P.E.P. 2173.05(u).

For these reasons, the rejection of claims 1-5, 13-18, 41-42, and 45 under 35 U.S.C. § 112, second paragraph cannot stand and should be withdrawn.

In view of the foregoing remarks, Applicants respectfully submit that the claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

Respectfully Submitted,

KENYON & KENYON LLP

Date: September 5, 2006

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